

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MITSUBISHI CHEMICAL CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION,
ENCYSIVE PHARMACEUTICALS INC.,
GLAXO GROUP LIMITED,
SMITHKLINE BEECHAM PLC, AND
SMITHKLINEBEECHAM PLC CORP. D/B/A
GLAXOSMITHKLINE,

Plaintiffs,

v.

BARR LABORATORIES, INC. AND
PLIVA-HRVATSKA D.O.O,

Defendants.

USDS SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: 4/29/08

Civil Action No. 1:07-CV-11614-JGK

Electronically Filed

~~[DRAFT]~~ STIPULATED PROTECTIVE ORDER

WHEREAS, the parties consider certain information and documents in their possession to be confidential and proprietary and, therefore, mutually desire that a protective order limiting use, access to and disclosure of such information and documents be entered, it is hereby ORDERED pursuant to Rule 26(c) of the Federal Rules of Civil Procedure as follows:

1. Any party or non-party providing discovery in this action may designate as "CONFIDENTIAL" any discovery material that contains trade secrets, and/or research, development, or commercial information (including financial and business information) that the party or non-party (or any predecessor in interest to a party or non-party) regards as confidential. CONFIDENTIAL material as used in this Order shall refer to the original and copies of any so designated document, testimony or other discovery material, and shall also refer to the

information contained in such material. All notes, extracts and summaries of CONFIDENTIAL material shall be considered CONFIDENTIAL material and be subject to the terms of this Order.

2. In designating information as CONFIDENTIAL, a party or non-party shall make such a designation only as to material that such party or non-party in good faith believes constitutes such material as matter used by it in, or pertaining to, its business, and that: (a) is material that is not generally known or otherwise available to the public, (b) is material that the party or non-party would normally not reveal to third parties or would cause third parties to maintain in confidence, or (c) is material otherwise entitled to protection under Rule 26(c) of the Federal Rules of Civil Procedure.

3. Any party or non-party providing discovery in this action may designate as "HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY" any discovery material that such party or non-party reasonably and in good faith believes is so highly sensitive that its disclosure would provide the recipient significant business or financial advantages. HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY information includes: information that qualifies as trade secrets within the meaning of the Uniform Trade Secrets Act; information concerning formulations; drug master file information submitted confidentially to the FDA and information related thereto; highly sensitive business information; information concerning methods of product preparation; highly sensitive non-public patent prosecution materials; and other information with a similar degree of confidentiality and value. HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY material as used in this Order shall refer to the original and copies of any so designated document, testimony or other discovery material, and shall also refer to the information contained in such material. All notes, extracts and summaries of HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY material shall be considered

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY material and be subject to the terms of this Order.

4. In designating information as HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY, a party or non-party shall make such a designation only as to highly sensitive material that such party or non-party in good faith believes constitutes such material as matter used by it in, or pertaining to, its business, and that: (a) is material that is not generally known or otherwise available to the public, (b) is material that the party or non-party would normally not reveal to third parties or would cause third parties to maintain in confidence, or (c) is material otherwise entitled to protection under Rule 26(c) of the Federal Rules of Civil Procedure.

5. In the event that any party disagrees at any time with a party or non-party's designation of information as CONFIDENTIAL or HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY such party shall provide to the producing party written notice of its disagreement with the designation. The producing party shall first try to dispose of such dispute in good faith on an informal basis. If the dispute cannot be resolved within ten (10) business days of receipt of the challenging party's written notice, the party challenging the designation may then request appropriate relief from the Court. The producing party who made the designation shall have the burden of proving that information has been properly designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY.

6. Discovery material designated as CONFIDENTIAL shall be maintained in confidence by the party or other authorized person to whom such material is produced or given and may be disclosed only to the following persons:

a. The Court and its officers, provided that any written submission to the court that discloses CONFIDENTIAL information shall be marked "CONFIDENTIAL" and shall be filed under seal as set forth in Paragraph 22 of this Order.

b. Outside counsel of record, employees of such outside counsel who are working under the direct supervision of such outside counsel, and outside vendors providing copying, coding, digitizing, translating and/or trial support services under a confidentiality agreement with such outside counsel.

c. Not more than three specifically identified, in-house attorneys employed by any of the defendants and not more than six specifically identified, in-house attorneys or intellectual property professionals¹ employed by any of the plaintiffs who are (a) actively working on or are responsible for this case, and (b) not involved in patent prosecution related in any way to the drug argatroban and (c) not a competitive decisionmaker for any party or any parent, subsidiary, or otherwise related entity with respect to any party, and such in-house counsel's or professional's legal assistants and secretaries working under the direct supervision of such in-house counsel or professional, provided that each such in-house counsel or professional has signed the undertaking annexed at Exhibit A or C as appropriate. The name, title and business address of such designated in-house counsel and intellectual property professionals shall be set forth in Exhibit B.

A party that seeks to designate an individual for qualification under this paragraph shall identify to the other parties such in-house attorney or intellectual property professional, by

¹ "Intellectual property professionals" shall refer to Japanese intellectual property professionals trained in intellectual property whose primary responsibilities include tasks typically performed by lawyers in the United States, including, e.g., litigation management, prosecution, and licensing.

name and title, and shall provide a description of such person's employment responsibilities.

The other parties shall have ten (10) business days from the receipt of this identification to object to such designation, stating the reasons for such objection. If an objection is timely made, the parties shall meet and confer within five (5) business days to attempt to resolve the issue. There shall be no disclosure of CONFIDENTIAL material to such identified individual until the issue is resolved either by the parties or by Court order. If the parties are unable to resolve the objection, the party seeking to make a designation may file a motion seeking a Court order permitting designation within ten (10) business days after the meet and confer. In the event that a designated in-house attorney or intellectual property professional ceases to be employed with a party to this action, that party shall have the right to substitute another designated individual, who shall meet the requirements identified herein, pursuant to the procedure set forth herein. In the event the employment responsibilities of a designated in-house attorney or intellectual property professional undergo a substantial change, the designating party shall notify the other parties of such change and shall provide an updated description of employment responsibilities, and the other parties shall have the opportunity to object as set forth in this paragraph.

d. Subject to the procedures set forth in paragraph 9, non-party experts, or other consultants who are not affiliated with a party and who are expressly engaged by outside counsel to provide expert testimony in this matter or to assist in discovery and/or preparation of this action for trial, with disclosure only to the extent necessary to perform such work ("outside consultants"), provided they have signed the undertaking annexed at Exhibit C; and

e. Any other person as to whom the producing party agrees in writing in advance of any disclosure.

7. Discovery material designated as HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY shall be maintained in confidence by the party or other authorized person to whom such material is produced or given and may be disclosed only to the following persons:

a. The Court and its officers, provided that any written submission to the court that discloses HIGHLY CONFIDENTIAL – ATTORNEYS EYES ONLY information shall be marked “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” and shall be filed under seal as set forth in Paragraph 22 of this Order;

b. Outside counsel of record, employees of such outside counsel who are working under the direct supervision of such outside counsel, and outside vendors providing copying, coding, digitizing, translating and/or trial support services under a confidentiality agreement with such outside counsel.

c. Subject to the procedures set forth in paragraph 9, non-party experts or other consultants who are not affiliated with a party and who are expressly engaged by outside counsel to provide expert testimony in this matter or to assist in discovery and/or preparation of this action for trial, with disclosure only to the extent necessary to perform such work (“outside consultants”), provided they have signed the undertaking annexed at Exhibit C; and

d. Any other person as to whom the producing party agrees in writing in advance of any disclosure.

8. In the event of any disclosure of CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material, other than in the manner authorized by this Order, counsel for the party responsible for the disclosure shall immediately notify counsel of the party who produced the material of the facts and circumstances of such disclosure,

including the identity of the unauthorized recipient(s) and the specific material disclosed to such person, and shall make every effort to prevent further unauthorized disclosure by, among other things, retrieving all such disclosed material and copies of such material and making good faith efforts to have all unauthorized persons to whom disclosure was made sign the undertaking annexed at Exhibit C.

9. Any person described in paragraph 6(d) or 7(c) is to be identified to the other party (with a copy of such disclosure sent to all other parties) before any CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material is shown to him or her. Such identification shall include a signed Undertaking in the form annexed as Exhibit C, and also shall provide the person’s resume or curriculum vitae and, if not included in the curriculum vitae, a summary of the person’s employment history for the past five years and description of every current or previous employment or consulting relationship with any of the parties. The party whose material is sought to be disclosed shall have ten (10) business days from the receipt of this identification to object to such disclosure, stating the reasons for such objection. If an objection is timely made, the parties shall meet and confer within five (5) business days to attempt to resolve the issue. There shall be no disclosure of such CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material until the issue is resolved either by the parties or by Court order. If the parties are unable to resolve the objection, the party seeking to make a disclosure may file a motion seeking a Court order permitting disclosure within ten (10) business days after the meet and confer.

10. No designation of documents, including the papers served and/or filed in this case, as CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY information shall be effective unless there is placed or affixed on such material the following

legend prior to its production: "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY." In the event that a producing party inadvertently fails to stamp or otherwise designate a document or other information as CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY at the time of its production, it may be corrected by written notification to opposing counsel; and provision of a copy of such document or information bearing the appropriate confidentiality designation, and the receiving party shall return or destroy the undesignated document or information and all copies thereof. Opposing counsel and other authorized recipients of such information shall not be responsible for any otherwise proper actions they took with respect to such information before receiving notice of the designation.

11. Testimony given at a deposition or hearing (including exhibits) may be designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY by an appropriate statement on the record at the time of the giving of such testimony, or by written notice given within thirty (30) days after receipt of the transcript by the counsel for the party whose CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY material was disclosed at the deposition or hearing. During the thirty-day review period, the transcript, including exhibits, shall be deemed HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY material. If there is no statement on the record designating the transcript or any portion of the transcript as CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY, and if no such designation is made within the thirty-day review period, the transcript shall not be considered as CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY material, except for designations inadvertently omitted, which may be corrected by written notification as set forth in paragraph 10.

12. All material designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY shall be used solely for the prosecution or defense of the claims in this action and shall not be used for any business, commercial, competitive, personal or other purpose, including patent prosecution. Counsel of record and the parties hereto shall take reasonable steps necessary to maintain such CONFIDENTIAL or HIGHLY CONFIDENTIAL ATTORNEYS’ EYES ONLY material in confidence and prevent persons from using, disclosing, or recording the CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material for any other purpose.

13. All CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material shall be stored in a secure and safe area and its custodians shall exercise the same standard of due and proper care with respect to the storage, custody, use and/or dissemination of such material as is exercised by the receiving party with respect to its own proprietary information, but no less than a reasonable standard of due and proper care, and shall be responsible for preventing any disclosure of such material, except in accordance with the terms of this Order.

14. After a final, non-appealable termination of this case, receiving outside counsel may retain copies of the pleadings, transcripts and exhibits, and may retain documents, things, copies, and samples to the extent they include or reflect receiving attorney’s work product. All other CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material produced by a party, and all copies, shall be returned to the producing party, or counsel of record for the receiving party shall certify in writing that such material has been destroyed within 30 days after the final termination of the case. The obligation on outside counsel to maintain the confidentiality of material designated as CONFIDENTIAL or HIGHLY

CONFIDENTIAL – ATTORNEYS’ EYES ONLY pursuant to this Order shall be deemed continuing.

15. The restrictions set forth in any of the paragraphs of this Order shall not apply to information or material that may have been produced in discovery in this lawsuit and designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY if that information or material: (a) was, is, or becomes public knowledge, not in violation of this Order; (b) is lawfully acquired by the non-designating party from a third party having the right to disclose such information or material independent of the producing party; or (c) was lawfully possessed by the non-designating party prior to entry by the Court of this Order.

16. Notwithstanding any other provision of this Order, at a deposition or trial in this action, (a) a party or present employee of a party may be examined and may testify concerning all CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material produced by that party; (b) a former employee of a party may be examined and may testify concerning all CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material produced by that party that clearly appears on its face or from other documents or testimony to have been prepared by, received by, known by or communicated to the former employee, or if counsel has a good-faith basis to believe the former employee has prior knowledge of the information contained in the document; and (c) non-parties may be examined and may testify concerning any document containing CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY information of a producing party that clearly appears on its face or from other documents or testimony to have been prepared by, received by, known by or communicated to the non-party.

17. Each person who receives any CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material in accordance with any provision of this Order hereby agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any proceeding relating to the performance under, compliance with, or violation of, this Order.

18. Any party may at any time seek modification of this Order or may challenge the propriety of a designation, by agreement, or failing agreement, by motion to the Court, pursuant to the federal and local rules.

19. The provisions of this Order shall be available for application to non-parties who are required to produce confidential information in response to a subpoena, and who in good faith believe that such material contains confidential information. Any party to this action or a non-party may designate information produced by the non-party as CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY within ten (10) business days of receipt of the information produced by the non-party. During the ten-day period, such information shall be deemed HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material. If no such designation is made within the ten-day period, such information shall not be considered to contain CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY material, except for designations inadvertently omitted, which may be corrected by written notification as set forth for producing parties in paragraph 10.

20. In the event a party has information that is subject to discovery and that is subject to contractual or other obligations of confidentiality owed to a third party, such party shall request in writing, the permission of the third party to produce such information subject to the terms of this Protective Order. If permission is denied, the producing party shall notify the

requesting party of such denial within ten (10) business days of receipt of such denial. The requesting party may seek any appropriate relief from this Court or another court and may pursue any other appropriate avenues of relief.

21. Documents or other materials produced in this case shall be produced in compliance with any local or regional law involving data protection or privacy.

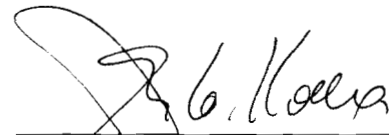
22. Information designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY shall be filed with the Court under seal. The parties are obligated to comply with the procedures for filing documents under seal, pursuant to the Procedure (No. 6) for Electronic Case Filing for the United States District Court, Southern District of New York.

23. Nothing herein shall preclude timely compliance with a subpoena issued by a government entity or Court order. In the event any party having possession, custody, or control of any document or information produced in this action and designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY receives a subpoena or other process or order to produce such information, such subpoenaed person or entity shall immediately notify by overnight delivery, facsimile or electronic mail the attorneys of record of the party that produced such CONFIDENTIAL or HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY material and shall furnish those attorneys with a copy of said subpoena or other process or order, and shall cooperate with respect to any procedure sought to be pursued by the party whose interest may be affected. The party asserting confidential treatment shall have the burden of defending against such subpoena, process, or order. Subject to any reasonable procedure sought to be pursued by the party whose interest may be affected, the person or party receiving the subpoena or other process or order shall be entitled to comply

with it except to the extent the party asserting the confidential treatment is successful in obtaining an order modifying or quashing it.

24. This Stipulated Protective Order is not binding on the Court or Court personnel. The Court reserves the right to amend this Protective Order at any time.

It is so ordered this 28 day of April, 2008



Hon. John G. Koeltl
United States District Judge

*This Order is not binding on the Court
& Court personnel. The Court reserves
the right to amend this Order at
any time.*

*So ordered
JG Koeltl
4/28/08 U.S.D.J.*